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REMARKS

Favorable reconsideration is respectfully requested in view of the preceding amendments and the following remarks. The Office Action indicated that claims 34-49 remained in the application and were rejected; however, claim 43 had been canceled in the Applicant's Response filed on November 28, 2000. Thus, claims 34-42 and 44-49 were pending at the time the Office Action was mailed.

Claims 36, 37, 40, 41, 48 and 49 have been canceled. Applicant does not concede the propriety of the rejections that were applied to these claims and reserves the right to pursue such claims or other claims directed to the subject matter thereof in a related application. Claims 44 and 45 have been rewritten in independent form to include all limitations of claims 36 and 37, respectively.

Claims 34-41 and 46-49 stand rejected under 35 U.S.C. § 112, first paragraph. This rejection has been obviated by the amendment, without prejudice, of those claims which have not been canceled to recite "viral RNA."

Claim 49 stands rejected under 35 U.S.C. § 135(b) over Wang et al. Claim 49 has been canceled.

Claims 37, 41 and 48 stand rejected under 35 U.S.C. §§ 102(b) and (e) over the Mullis et al. '195 patent. These claims have been canceled.

Claims 36 and 40 stand rejected under 35 U.S.C. § 103(a) over Mullis et al. '195 in view of the kit description in the 1988 Strategene Catalog. These claims have been canceled.

Claims 35-37, 39-41 and 43-45 stand provisionally rejected under 35 U.S.C. § 101 as claiming the same invention claimed in Applicant's application serial no. 08/769,584. Contemporaneously with the filing of this Amendment, Applicant has filed an express abandonment of the '584 application. A copy of the express abandonment paper is enclosed herewith for the Examiner's convenience. This obviates the rejection.

Claims 34-39 stand provisionally rejected under the "obviousness-type double patenting doctrine over the claims of application serial no. 08/769,584. The abandonment of the '584 application obviates the rejection.

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Conclusion

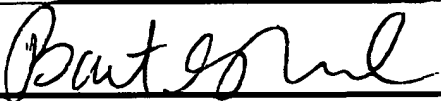
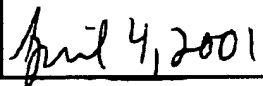
It is respectfully submitted that, following the entry of the foregoing amendments, all claims will be in condition for the Examiner to act upon the Requests for Interference. The Section 112 rejection has been addressed by amendment of the claims to recite "viral RNA," the co-pending '584 application has been abandoned, and all claims that were subject to art-based rejections have been canceled. None of the foregoing amendments affect the Request for Interference, and the Requests for Interference presented in Applicant's Amendment and Request for Interference (Dec. 18, 1996), Supplemental Preliminary Amendment and Request for Interference (Jan. 9, 1998), and Amendment and Response (Nov. 28, 2000) are incorporated herein. More particularly, the present claims, which are directed to reaction mixtures, plasmids and kits for the quantitative amplification of viral RNA, if entitled to an earlier priority, are not patentably distinct from those of the '774 patent and the proposed count. The '774 claims and the proposed count are directed to a genus -- the amplification of nucleic acids -- and the instant claims are directed to a species falling within that genus -- the amplification of viral RNA. Accordingly, using the analysis mandated by 37 C.F.R. § 1.601(n), the subject matter of the instant claims, if prior art to the '774 patent claims and proposed count, would anticipate. Therefore, the '774 patent claims and the proposed count are not patentably distinct from the instant claims, and an interference should be declared. It remains Applicant's belief that all claims remaining in this application should be designated as corresponding to the proposed Count for the reasons set forth in the earlier-filed Requests for Interference referenced above.

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Early and favorable action on the Request for Interference is respectfully requested.

| RESPECTFULLY SUBMITTED. | | | | | |
|-------------------------|---|-----------|--------------|----------|---|
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| SIGNATURE |  | | | DATE |  |
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Attachments: Marked-Up Copies of Amendments

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Amended Claims: Version with markings to show changes made

34. (Twice Amended) An amplification reaction mixture for the quantitation of a target ~~viral~~ RNA segment in a biological sample, said reaction mixture comprising:

said target ~~viral~~ RNA;

a predetermined initial amount of a control sequence for quantitation of a target ~~viral~~ RNA, wherein said control sequence and its complementary sequence bind the same primers as are bound by said target ~~viral~~ RNA segment and its complementary sequence; and

an oligonucleotide primer pair wherein said primer pair can serve to amplify said control sequence and said target ~~viral~~ RNA, wherein following amplification said control sequence and amplified target segments are distinguishable by size.

35. (Twice Amended) A reverse transcription reaction mixture for reverse transcribing a target mRNA suspected of being present in a biological sample, said reaction mixture comprising a predetermined initial amount of a control sequence cRNA, a target ~~viral~~ RNA, and a target-specific primer for initiating cDNA synthesis, wherein said primer can serve to initiate reverse transcription of a nucleic acid segment contained within said control sequence cRNA together with a segment contained within the particular target ~~viral~~ RNA, and wherein said control sequence is further distinguished by having a hybridization site identical in sequence to a hybridization site in said target ~~viral~~ RNA, whereby following reverse transcription the resulting target and control sequence cDNAs can serve as templates for amplification for providing control sequence and target amplified ~~viral~~ RNA segments which are distinguishable by size.

42. (Twice Amended) The mixture of claim 34, wherein the target ~~viral~~ RNA is contained within a nucleic acid sequence which encodes a protein associated with HIV or HCMV.

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44. (Twice Amended) The kit of claim 36, ~~A kit for the quantitation of a target viral RNA segment in a biological sample comprising individual containers which provide:~~

~~a predetermined initial amount of a control sequence for quantitation of a target viral RNA wherein said control sequence binds the same primers as are bound by said target viral RNA segment and its complementary sequence, and an oligonucleotide primer pair wherein said primer pair can serve to amplify said control sequence and said target viral RNA~~
~~wherein following amplification said control sequence and target amplified viral RNA segments are distinguishable by size or by use of an internal oligonucleotide probe, and~~ wherein the target viral RNA is contained within a nucleic acid sequence which encodes a protein associated with HIV or HCMV.

45. (Twice Amended) The plasmid of claim 37, ~~A plasmid for use as an internal control for quantitation of a target viral RNA sequence contained within a sample which plasmid comprises:~~
~~a control sequence comprising two sequences which provide primer hybridization sites in said plasmid which primer hybridization sites are identical to primer hybridization sites within said target viral RNA sequence such that a primer pair will function in a PCR reaction to amplify said control sequence and said target viral RNA segment, wherein upon amplification said control sequence and said target segments can be distinguished by size, and~~ wherein the target viral RNA is contained within a nucleic acid sequence which encodes a protein associated with HIV or HCMV.

46. (Twice Amended) An amplification reaction mixture for the quantitation of a target viral RNA segment in a biological sample, said reaction mixture comprising:
said target viral RNA;

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a predetermined initial amount of a control sequence for quantitation of a target ~~viral~~ RNA, wherein said control sequence binds the same primers as are bound by said target ~~viral~~ RNA segment; and

an oligonucleotide primer pair wherein said primer pair can serve to amplify said control sequence and said target ~~viral~~ RNA, wherein following amplification said control sequence and target amplified ~~viral~~ RNA segments are distinguishable by size or by the use of internal hybridization probes.

47. (Twice Amended) A reverse transcription reaction mixture for reverse transcribing a target mRNA suspected of being present in a biological sample, said reaction mixture comprising a predetermined initial amount of a control sequence cRNA, a target ~~viral~~ RNA, and a target-specific primer for initiating cDNA synthesis, wherein said primer can serve to initiate reverse transcription of a nucleic acid segment contained within said control sequence cRNA together with a segment contained within the particular target ~~viral~~ RNA, and wherein said control sequence is further distinguished by having a hybridization site identical in sequence to a hybridization site in said target ~~viral~~ RNA, whereby following reverse transcription the resulting target and control sequence cDNAs can serve as templates for amplification for providing control sequence and target amplified ~~viral~~ RNA segments which are distinguishable by size or by use of internal hybridization probes.